REMARKS

The Office Action mailed September 17, 2007, has been received and reviewed. Claims 2, 3, 6, 9 through 19, 21 through 35, 37 through 47 and 49 through 84 are currently pending in the application, of which claims 2, 3, 6, 9 through 19, 28 through 35, 37 through 47 and 49 through 84 are currently under examination. Claims 21 through 27 and 49 through 83 are withdrawn from consideration as being drawn to a non-elected invention, and Claims 1, 4, 5, 7, 8, 20, 36 and 48 have been canceled. Applicants respectfully request reconsideration of the application as amended herein.

35 U.S.C. § 103(a) Obviousness Rejections

Obviousness Rejection Based on U.S. Patent No. 6,331,311 to Brodbeck et al. in view of U.S. Patent No. 6,130,200 to Brodbeck et al. and Polymer International 1998, Vol. 46, pp. 203-216 by Penco et al.

Claims 2, 3, 6, 9 through 19, 28 through 35, 37 through 47 and 84 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Brodbeck et al. (U.S. Patent No. 6,331,311) (hereafter "'311 Patent") in view of Brodbeck et al. (U.S. Patent No. 6,130,200) (hereafter "'200 Patent") and Penco et al. (Polymer International 1998, Vol. 46, pp. 203-216) (hereafter "Penco"). Applicants respectfully traverse this rejection, as hereinafter set forth.

U.S. Patent No. 6,331,311 to Brodbeck et al. (hereinafter "Brodbeck") has not been made of record herein. Therefore, according to a telephone conference between Examiner Arnold and TraskBritt paralegal, Doreen Neumann, Examiner Arnold instructed Ms. Neumann to include the Brodbeck reference in a Supplemental Information Disclosure Statement that she was already preparing to be filed in this matter.

To establish a *prima facie* case of obviousness the prior art reference (or references when combined) **must teach or suggest all the claim limitations**. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974); *see also* MPEP § 2143.03. Additionally, there must be "a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742, 167 L.Ed.2d 705, 75 USLW 4289, 82 U.S.P.Q.2d 1385 (2007). Finally, to establish a *prima facie* case of obviousness

there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Furthermore, the reason that would have prompted the combination and the reasonable expectation of success must be found in the prior art, common knowledge, or the nature of the problem itself, and not based on the Applicant's disclosure. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006); MPEP § 2144. Underlying the obvious determination is the fact that statutorily prohibited hindsight cannot be used. *KSR*, 127 S.Ct. at 1742; *DyStar*, 464 F.3d at 1367.

The '311 Patent is relied upon as teaching an injectable depot gel composition comprising a biocompatible polymer having a number average molecular weight of from 1,000 to 120,000, an organic solvent and a beneficial agent dispersed in the gel. (Office action at pg. 3). As acknowledged by the Examiner, the '311 Patent does not teach or suggest "mixtures of high, medium and low molecular weight lactic acid based polymers in the injectable drug depot" and, further, does not teach or suggest use of benzyl alcohol as a solvent." (*Id.* at pg. 4).

To cure the lack of teaching for a mixture of high, medium and low molecule are weight lactic acid based agents dispersed in a gel, the Examiner relies on the teachings of the '200 Patent. However, the '200 Patent does not overcome the deficiencies of the '311 Patent. As acknowledged by the Examiner, the '200 Patent teaches a gel composition comprising "a biocompatible polymer," and a biocompatible solvent with low water miscibility that forms a gel with the polymer and a beneficial agent. (*Id.*). The Examiner relies specifically on claim 15 for a teaching that "the copolymer has a number average molecular weight of from 1,000 to 120,000 (claims 15)." (*Id.*). However, the teaching of a "number average molecular weight of from 1,000 to 120,000" in both the '200 Patent and the '311 Patent are expressly drawn to a single polymer. As evidenced throughout the Specification and the Claims of the '200 Patent and the '311 Patent, the teaching of a 1,000 to 120,000 average molecular weight range is specifically in reference to the single polymer or lactic acid based polymer. There is no disclosure, teaching or suggestion in either the '200 Patent or the '311 Patent that has been cited or that can be found relating to a polymer matrix comprising a plurality of bioerodible, biocompatible lactic acid-based polymers; wherein a first of the plurality of polymers is a low molecular weight (LMW) polymer; and a second of the plurality of polymers is a high molecular weight (HMW) polymer; the polymer

matrix having a bimodal molecular weight distribution of the plurality of polymers, (either alone or in combination with the additional limitations) as required in all of the independent claims pending in the current matter.

To cure the lack of teaching for use of benzyl alcohol as a solvent, the Examiner relies on Penco. Penco is specifically relied upon as teaching benzyl alcohol as a known solvent for PLGA. However, Penco does not overcome the deficiencies of the '311 Patent and the '200 Patent with regard to the limitation drawn to mixtures of high, medium and low molecular weight lactic acid based polymers in the injectable drug depot, as required by all of the pending claims.

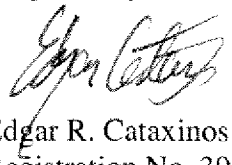
Applicant submit that the combination of the '311 Patent, the '200 Patent, and Penco do not teach or suggest all of the limitations of the pending claims. In view of the foregoing, Applicants respectfully request withdrawal of the present rejection to claims 2, 3, 6, 9-19, 28-35, 37-47, and 84.

CONCLUSION

Claims 2, 3, 6, 9-19, 28-35, 37-47, and 84are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that

additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,



Edgar R. Cataxinos
Registration No. 39,931
Attorney for Applicants
TRASKBRITT
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

Date: December 17, 2007
ERC/dn:tlp
Document in ProLaw